

Applicant is advised that the previous Examiner who examined this application is no longer employed by the USPTO, and the application has been transferred to the undersigned Primary Examiner. Upon review of the record and prosecution history, it has been determined that a new restriction and election of species requirement are necessary. MPEP 811-811.04.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 7-8, drawn to a medical implant comprising a crosslinked hydrogel, wherein the crosslinked hydrogel is a protein.
- II. Claims 9-10, drawn to a medical implant comprising a crosslinked hydrogel, wherein the crosslinked hydrogel is a polysaccharide.
- III. Claims 12, 14, 26-27, 34-35, 42-43 and 59-60, drawn to a medical implant comprising a crosslinked hydrogel polymerized from at least one macromer, wherein the macromer, before polymerization, comprises a synthetic hydrophilic polymer.
- IV. Claims 16, 29, 52, 55, 61, drawn to a medical implant comprising a crosslinked hydrogel polymerized from at least one macromer, wherein the hydrogel comprises at least a portion that is biphasic.
- V. Claims 17 and 51, drawn to a medical implant comprising a crosslinked hydrogel polymerized from at least one macromer, wherein the hydrogel comprises a hydrophobic liquid or a gas.

- VI. Claims 18, 19 (assuming that it should properly depend on claim 18), 62 and 63, drawn to a medical implant comprising a crosslinked hydrogel polymerized from at least one macromer, wherein the hydrogel comprises bubbles.

Applicant is **further required to elect a distinct species of crosslinked hydrogel or macromer precursor within each of the invention groups**. For example, if Group III were elected, the elected species could be a poly(ethylene glycol) diacrylate macromer.

Claims 1-5, 11, 13, 15, 20-25, 28, 30-33, 36-40, 41, 44-50, 53-54, 56-58 and 64-72 link inventions I, II, III, IV, V and VI. Claim 6 additionally links invention I. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claims, claims 1-6, 11, 13, 15, 20-25, 28, 30-33, 36-40, 41, 44-50, 53-54, 56-58 and 64-72 as noted above. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are

governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The six inventions are distinct because they each utilize distinct hydrogels, which are used to form medical implants. Medical implants made of distinct materials are separate and distinct inventions.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

It is noted for the record that Mr. Herbert and the Examiner were in discussion on 3/25/2008 and 3/28/2008 as to claim amendments that may possibly advance prosecution. The Examiner stated that a new restriction requirement would have to be issued if an agreement could not be reached. An agreement could not be timely reached before the due date for this Office action. See the attached Interview Summary Record.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616